Amendment No. 1 to SB3627

## <u>Crowe</u> Signature of Sponsor

AMEND Senate Bill No. 3627

House Bill No. 2801\*

by deleting all language after the enacting clause and by substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 6, is amended by adding a new section to read as follows:

63-6-242.

(a)

- (1) "Hormone replacement therapy clinic" or "hormone therapy clinic" means a medical office in which the clinicians are primarily engaged in hormone replacement or supplementation therapy or a medical office which holds itself out to the public as being primarily or substantially engaged in hormone replacement therapy. For the purposes of this definition, the phrase "primarily engaged" means that a majority of the clinic's patients receive hormone replacement therapy and may be further defined by the board by rule. Hormone replacement therapy clinic does not mean a medical office in which the clinicians are primarily engaged in obstetrics and gynecology (OB/GYN), urology or primary care.
- (2) "Hormone replacement therapy" or "hormone therapy" means the branch of the practice of medicine whereby the patient is treated with medications that include, but are not limited to, creams or natural formulas taken through the skin, under the tongue, in subcutaneous pellets, or orally that contain hormones that have the same bioidentical or similar chemical formula as those produced naturally in the human body

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or that the provider thinks or claims to be similar or identical, but shall not include the treatment of patients with birth control pills.

- (b) In hormone replacement therapy clinics:
- (1) All hormone replacement therapy shall be performed by a physician licensed under Title 63, Chapter 6 or 9, or delegated by such physician to a certified nurse practitioner licensed pursuant to Title 63, Chapter 7 or a physician assistant licensed pursuant to Title 63, Chapter 19; and
- (2) If hormone replacement therapy is delegated, the supervising physician shall ensure that written protocols are developed for licensees to whom hormone replacement therapy is delegated, that such protocols are updated as necessary and that the patient is informed of both the name and contact information of the supervising physician and an indication of whether the physician is available on-site or remotely.
- (c) A physician supervising hormone replacement therapy in a hormone replacement therapy clinic shall ensure that for each patient, all of the following requirements are met:
  - (1) Prior to the initial hormone replacement therapy or course of treatments, an appropriate physical examination shall be conducted;
  - (2) An appropriate medical history shall be taken and documented on the patient;
  - (3) A written order for hormone replacement therapy shall be entered by the treating provider in the patient's medical record documenting the diagnosis and medical reason for the patient's need for

hormone replacement therapy. If the treating provider is not a physician, the supervising physician shall make a personal review of the historical, physical and therapeutic data gathered by the treating provider and shall so certify the review in the patient's chart within seven (7) days of the patient being served;

- (4) The patient gives written consent for hormone replacement therapy, which includes notification of possible complications and reasonable expectations and any applicable FDA warnings associated with any part of the therapy; and
- (5) The supervising physician shall be immediately notified upon discovery of a complication.

SECTION 2. Tennessee Code Annotated, Title 63, Chapter 9, is amended by adding a new section to read as follows:

63-9-119.

(a)

- (1) "Hormone replacement therapy clinic" or "hormone therapy clinic" means a medical office in which the clinicians are primarily engaged in hormone replacement or supplementation therapy or a medical office which holds itself out to the public as being primarily or substantially engaged in hormone replacement therapy. For the purposes of this definition, the phrase "primarily engaged" means that a majority of the clinic's patients receive hormone replacement therapy and may be further defined by the board by rule. Hormone replacement therapy clinic does not mean a medical office in which the clinicians are primarily engaged in obstetrics and gynecology (OB/GYN), urology or primary care.
- (2) "Hormone replacement therapy" or "hormone therapy" means the branch of the practice of medicine whereby the patient is treated with

medications that include, but are not limited to, creams or natural formulas taken through the skin, under the tongue, in subcutaneous pellets, or orally that contain hormones that have the same bioidentical or similar chemical formula as those produced naturally in the human body or that the provider thinks or claims to be similar or identical, but shall not include the treatment of patients with birth control pills.

- (b) In hormone replacement therapy clinics:
- (1) All hormone replacement therapy shall be performed by a physician licensed under Title 63, Chapter 6 or 9, or delegated by such physician to a certified nurse practitioner licensed pursuant to Title 63, Chapter 7 or a physician assistant licensed pursuant to Title 63, Chapter 19; and
- (2) If hormone replacement therapy is delegated, the supervising physician shall ensure that written protocols are developed for licensees to whom hormone replacement therapy is delegated, that such protocols are updated as necessary and that the patient is informed of both the name and contact information of the supervising physician and an indication of whether the physician is available on-site or remotely.
- (c) A physician supervising hormone replacement therapy in a hormone replacement therapy clinic shall ensure that for each patient, all of the following requirements are met:
  - (1) Prior to the initial hormone replacement therapy or course of treatments, an appropriate physical examination shall be conducted;
  - (2) An appropriate medical history shall be taken and documented on the patient;
  - (3) A written order for hormone replacement therapy shall be entered by the treating provider in the patient's medical record documenting the diagnosis and medical reason for the patient's need for

hormone replacement therapy. If the treating provider is not a physician, the supervising physician shall make a personal review of the historical, physical and therapeutic data gathered by the treating provider and shall so certify the review in the patient's chart within seven (7) days of the patient being served;

- (4) The patient gives written consent for hormone replacement therapy, which includes notification of possible complications and reasonable expectations and any applicable FDA warnings associated with any part of the therapy; and
- (5) The supervising physician shall be immediately notified upon discovery of a complication.

SECTION 3. If any provision of this act or the application thereof to any person or circumstances is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provisions or application, and to that end the provisions of this act are declared to be severable.

SECTION 4. This act shall take effect on July 1, 2012, the public welfare requiring it.